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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,021	01/30/2006	Yukoh Sakata	19331-002US1 OSP-18070	7382
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EXAMINER SASAN, ARADHANA				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
12/11/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

### Office Action Summary

**Application No.**

10/539,021

**Applicant(s)**

SAKATA ET AL.

**Examiner**

ARADHANA SASAN

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5.7.11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5.7.11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Application***

1. The remarks and amendments filed on 07/17/08 are acknowledged.
2. Claims 1-4, 6, 8-10, 12-13 and 19-20 were cancelled.
3. Claims 5 and 14 were amended.
4. Claims 5, 7, 11 and 14-18 are included in the prosecution.

***Response to Arguments***

**Objection to claim 20**

5. In light of Applicant's cancellation of claim 20, the objection of 03/18/08 is moot.

**Rejection of claims 1-9, 14-17 and 19-20 under 35 USC § 102(b)**

6. Applicant's arguments, see page 4, filed 07/17/08, with respect to the rejection of claims 1-9, 14-17 and 19-20 under 35 U.S.C. § 102(b) as being anticipated by Kawata et al. (US 3,798,054) have been fully considered and are persuasive. The rejection of 03/18/08 has been withdrawn.
7. Regarding instant claim 14, a new ground of rejection is made under 35 USC 103(a) in view of Iwata et al. (WO 01/40182 A2). Since this new ground of rejection was necessitated by Applicant's amendment, this action is made FINAL.

**Rejection of claims 1-3, 5-13 and 15-20 under 35 USC § 102(b)**

8. Applicant's arguments, see page 5, filed 07/17/08, with respect to the rejection of claims 1-3, 5-13 and 15-20 under 35 U.S.C. § 102(b) as being anticipated by Iwata et al. (WO 01/40182 A2) have been fully considered but are not found persuasive.

Applicant argues that nowhere does Iwata disclose a composition that includes a water-soluble calcium salt and a water soluble cellulose base polymer, which can be formulated for forming a film.

This is not found persuasive because Iwata teaches calcium sulfate (Page 24, line 24). Calcium sulfate is a water soluble calcium salt. The instant specification also discloses calcium sulfate as a preferable calcium salt (Page 4, 3<sup>rd</sup> full paragraph). Iwata also teaches hydroxypropylmethylcellulose, hydroxypropylcellulose and methylhydroxyethyl-cellulose (Page 24, lines 5-11), which are water soluble cellulose base polymers. Iwata teaches that coloring agents, such as calcium sulfate, may be added into the coating agent, which includes the water soluble cellulose polymers stated above.

Since all the limitations of amended claim 5 and claims 7, 11 and 15-18 are anticipated by Iwata; the rejection of 03/04/08 is maintained.

#### **MAINTAINED REJECTIONS**

#### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 5, 7, 11 and 15-18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Iwata et al. (WO 01/40182 A2).

The claimed invention is a film-forming composition comprising a calcium-containing compound and a film-forming base agent, wherein the calcium-containing compound is a water-soluble calcium salt and the film-forming base agent is a water-soluble cellulose base polymer.

Iwata teaches a solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17). Iwata teaches polymeric film coating of the tablets where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Iwata also teaches that "in order to protect from light or to improve the discriminability, a suitable coloring agent may be added into a coating agent. Calcium sulfate is disclosed as a coloring agent that may be used (Page 24, lines 19-24).

Therefore, all the limitations of claims 5, 7, 11 and 15-18 are anticipated by the teachings of Iwata.

## **NEW REJECTIONS**

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata et al. (WO 01/40182 A2).

The teaching of Iwata is stated above.

Iwata does not expressly teach the calcium salt in an amount of 0.1 to 150% by weight, relative to a weight of the film-forming base agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a solid preparation that may be tablets, capsules or granules with a coating of water soluble polymers such as hydroxypropylmethylcellulose, hydroxypropylcellulose, and methylhydroxyethyl-cellulose and coloring agents such as water soluble calcium sulfate, as suggested by Iwata, modify the level of calcium sulfate to achieve the desired coloring effect during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwata teaches that coloring agent (such as calcium sulfate) may be added into the coating in order to "protect from light or to improve the discriminability" of the product (Page 24, lines 19-24).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 14, the limitation of the calcium salt in an amount of 0.1 to 150% by weight, relative to a weight of the film-forming base agent would have been obvious to one skilled in the art over the calcium salt that is disclosed by Iwata (Page 24, lines 19-24). One of ordinary skill will vary the level of calcium salt in the coating

composition in order to achieve the desired coloring or discriminability effect. The recited percentage range is extremely broad and would be obvious absent evidence or criticality or unexpected results.

### ***Conclusion***

13. No claims are allowed.
14. Since this new rejection was necessitated by applicant's amendment, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615